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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,250	10/06/2005	May Griffith	OHR5-001US	4662

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	**PAPER NUMBER**
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,250	GRIFFITH ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50 and 111-117* is/are pending in the application.

4a) Of the above claim(s) *13-48,50 and 111-117* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/24/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I claims 1-12, 49 and 111 the species of a copolymer comprising N-isopropylacrylamide and N-acryloxysuccinimide and acrylic acid in the replies filed on 05/13/2009 and 09/08/2009 is acknowledged. The examiner notes that claim 111 which is drawn to the copolymer should have been included in group I and is included here. The traversal is on the ground(s) that US 46114701 does not teach the copolymer having pending cross-linkable moieties reactive with primary amines. This is not found persuasive because the recitation of cross-linkable moieties reactive with primary amines is just a functional limitation that the examiner will consider met if the polymer is within the same claimed scope. As detailed in the office action on 03/13/2009 the copolymer described in US 46114701 is within applicants claimed scope.

Claims 13-48, 50 and 111 (nonelected species) and 112-117 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species or invention, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

Response to Amendment

Applicants amendments to the claims filed 10/06/2005 have been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically the average molecular mass range in line 5 is unitless, e.g. are the units in Daltons, Kilo Daltons etc. In the interest of compact prosecution the examiner will assume the average MW unit is Daltons.

Claim 5 recites the limitation "alkyl or lower alkyl" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The examiner notes that the references below do not read on the specific polymer species elected, however in the interest of compact prosecution the examiner has included the following references found during his search which anticipate the broader claims.

Claims 1-3,5,8-11 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Uludag et al. (J. Appl. Polym. Sci., 75:583-592 (2000), cited by applicants).

Uludag teaches copolymers of NiPAAM and N-acryloxysuccinimide (ASI) with molecular weights ranging from 7.1 to 26.6 kDa. See entire document including table 1. It is noted by the examiner that in claim 3 the hydrophilic monomer and N-alkyl or N.N-

dialkyl can be the same, thus NiPAAM alone meets both limitations. As noted in applicants specification N-acryloxysuccinimide is a monomer with a pendant crosslinkable moiety (succinimide) that is reactive with primary amines. See [0056] of US 20060134050 A1, the US pub of applicant's application).

Claims 1-3,5,8-11 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Percot et al. (Polymer 41 (2000) 7231-7239).

Percot teaches hydrogels made of copolymers of NiPAAM and N-ASI with molecular weight of 12 and 32 kDa. See entire document including table 1. It is noted by the examiner that in claim 3 the hydrophilic monomer and N-alkyl or N.N- dialkyl can be the same, thus NiPAAM alone meets both limitations. As noted in applicants specification N-acryloxysuccinimide is a monomer with a pendant crosslinkable moiety (succinimide) that is reactive with primary amines. See [0056] of US 20060134050 A1, the US pub of applicant's application).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elaissari et al. (US 7,060,804 B2).

Elaissari discloses magnetic colloidal particles containing a core which comprises a metal and a polymer coat, the polymer coat included NiPAAm, the particle further comprised an envelope in which a copolymer of acrylic acid and N-acryloxysuccinimide could be selected. See claims, especially 1,3-4,9-10 and 13. The polymer coat from the core and envelope contain functional groups that allow the core and envelope to at least partially react forming a larger copolymer type of network, thus a copolymer of NiPAAm acrylic acid and N-acryloxysuccinimide could be selected from the claimed invention. As noted in applicants specification N-acryloxysuccinimide is a monomer with a pendant crosslinkable moiety (succinimide) that is reactive with primary amines. See [0056] of

US 20060134050 A1, the US pub of applicant's application). Elaissari is silent on the molecular weight and molar ratios of the monomer components as required in claims 1 and 6-7. However, the molecular weight and percentage or the ratio of specific ingredients in this composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal molecular weight and amount of each ingredient in the polymer needed to achieve the desired results. Such parameters that could be optimized by selecting the optimal molecular weight and amount of each ingredient in the polymer could be tensile strength, hardness, hydrophobicity and hydrophillicity of the polymer. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. It is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket,* 33 USPQ 33; *In re Russell,* 169 USPQ 426.

Claims 1-12 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Percot et al. (Polymer 41 (2000) 7231-7239) in view of Stile et al. (Macromolecules 1999, 32, 7370-7379, cited by applicants).

Percot is disclosed above. Percot does not describe the use of acrylic acid in the copolymers described.

Stile describes hydrogels based upon NiPAAm and acrylic acid (AAc). See entire document especially abstract. The NiPAAm-AAc copolymers demonstrated significantly

less volume change between RT and 37° C, contained significantly more water at 37° C and had a lower critical solution temperature (LCST) compared to a hydrogel comprising only NiPAAm. Stile suggested that such a hydrogel with the above properties would be useful in injectable polymer scaffolds for tissue engineering applications. Since both references are related to the same general field of endeavor and the reactivities of all the monomers claimed were well known one of ordinary skill in the art would have a reasonable expectation of success in adding AAc monomer to NiPAAM-co-N-ASI copolymer described in Percot to form the copolymer NiPAAM-co-ASI-co-N-ASI. The reason to make such a modification to Percot is to change the physical properties of the hydrogel for use as an injectable polymer scaffold in tissue engineering applications. Thus the claimed invention would have been *prima facie* obvious since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Regarding claims 6-7 which limit the molar ratios of the monomer components, the percentage or the ratio of specific ingredients in this composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient in the polymer needed to achieve the desired results. Such parameters for the hydrogel that could be optimized by selecting the optimal molecular weight and

amount of each ingredient in the polymer hydrogel could be tensile strength, LCST, hardness, hydrophobicity and hydrophillicity (water absorption). Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. It is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket,* 33 USPQ 33; *In re Russell,* 169 USPQ 426.

Claims 1-12 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uludag et al. (J. Appl. Polym. Sci., 75:583-592 (2000)) in view of Stile et al. (Macromolecules 1999, 32, 7370-7379).

Uludag is disclosed above. Uludag does not describe the use of acrylic acid in the copolymers described.

Stile describes hydrogels based upon NiPAAm and acrylic acid (AAc). See entire document especially abstract. The NiPAAm-AAc copolymers demonstrated significantly less volume change between RT and 37^{o} C, contained significantly more water at 37^{o} C and had a lower critical solution temperature (LCST) compared to a hydrogel comprising only NiPAAm. Stile suggested that such a hydrogel with the above properties would be useful in injectable polymer scaffolds for tissue engineering applications. Since both references are related to the same general field of endeavor and the reactivities of all the monomers claimed were well known one of ordinary skill in the art would have a reasonable expectation of success in adding AAc monomer to NiPAAM-co-N-ASI described in Uludag to form the copolymer NiPAAM-co-ASI-co-N-

ASI. The reason to make such a modification to Uludag is to change the physical properties of the hydrogel to for use as an injectable polymer scaffold in tissue engineering applications. Thus the claimed invention would have been *prima facie* obvious since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Regarding claims 6-7 which limit the molar ratios of the monomer components, the percentage or the ratio of specific ingredients in this composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient in the polymer needed to achieve the desired results. Such parameters for the hydrogel that could be optimized by selecting the optimal molecular weight and amount of each ingredient in the polymer hydrogel could be tensile strength, LCST, hardness, hydrophobicity and hydrophillicity (water absorption). Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. It is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket,* 33 USPQ 33; *In re Russell,* 169 USPQ 426.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618